OCT 31 2000

K002361

3. Summary of Safety and Effectiveness Information:

Sponsor

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
Contact: Bonnie Smith

Device Name:

Synthes (USA)
Locking Proximal Tibia Plating (L-PTP) System

Device Classification:

21 CFR 888.3030 Single/multiple component metallic bone fixation appliance.

Predicate Device:

Synthes (USA) Proximal Tibia Plating System

Description of Device:

Synthes Locking Proximal Tibia Plating System is a plate and screw system. The plates are anatomically contoured with a limited contact, low-profile design. The primary feature of this system is a locking hole design in the head and shaft of the plate which accepts locking screws to form a locked, fixed angle construct. Locking holes also accept standard, non-locking Synthes screws, which facilitate reduction and create compression between plate and bone. The plates have overall lengths ranging from 100 mm to 244 mm and shaft holes ranging from 5 to 13.

The plates accept 5.0 Cannulated Locking Screws, 5.0 Cannulated Conical Screws, 4.5 mm Cortex or 6.5 mm Cancellous Screws, and 4.0 mm Locking Screws. Locking screws for locking holes are also interchangeable with standard, non-locking Synthes screws and may be used at the discretion of the surgeon.

Indications:

Synthes Locking Proximal Tibia Plating System is indicated for treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combination of lateral wedge and depression, and fractures with associated shaft fractures.

Material:

316L Stainless Steel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2000

Ms. Bonnie J. Smith, RAC
Senior Regulatory Affairs Associate
SYNTHES (USA)
P.O. Box 1766
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K002361
Trade Name: SYNTHES (USA) Locking Proximal Plating (L-PTP) System
Regulatory Class: II
Product Code: HRS
Dated: August 1, 2000
Received: August 3, 2000

Dear Ms. Smith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K002361

Device Name: Synthes (USA) Locking Proximal Tibia Plating (L-PTP) System

Indications for Use:

Synthes Locking Proximal Tibia Plating System is intended for treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combination of lateral wedge and depression, and fractures with associated shaft fractures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002361

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_
(Per 21 CFR 801.109)